

REMARKS

Claim 21 is the sole claim remaining in this application. This claim has been rejected under 35 U.S.C. § 102(a) as being anticipated by Mortimer (GB 2 131 292). Applicants request that the Examiner reconsider this rejection in view of the following comments.

Claim 21 defines a method for delivering folic acid to a subject for whom oral contraception is indicated. More specifically, a pharmaceutical preparation including an oral contraceptive for preventing pregnancy and folic acid is administered to a subject from a population whose members are afflicted with or are predisposed to become afflicted with cervical dysplasia or cervical carcinoma at a higher than normal incidence than the general population of subjects taking oral contraceptives. The pharmaceutical preparation administered according to the claimed method includes an amount of folic acid sufficient to treat or prevent the enumerated disorders. No such method is taught or suggested by Mortimer.

Mortimer is primarily concerned with a method for treating or preventing hair loss in men. To this end, Mortimer teaches the use of progestin formulations, in particular medroxyprogesterone acetate, together with vitamin and mineral supplements to treat or prevent male pattern baldness. Mortimer notes that progestins cause desquamation of superficial cells of the vaginal mucosa, inhibit ferning of the cervical mucosa and induce withdrawal bleeds in oestrogen primed women. Mortimer also observes that many individuals for whom progestin therapy is appropriate also benefit from treatment with folic acid. According to Mortimer, this is the case because such individuals often have poor diets due to depression because of their general medical condition and because such patients are often in need of new tissue growth or better fertility.

Mortimer's comments regarding the use of folic acid with progestins and the basis for such a combination fall far short of teaching or even suggesting the claimed method. As noted above, the method of claim 21 is limited to those individuals for whom oral contraception is indicated and in those specific instances where such individuals are also members of a population who are afflicted with or are predisposed to become afflicted with cervical dysplasia or cervical carcinoma at a higher than normal incidence. Mortimer nowhere mentions the administration of progestins in combination with oral contraceptives, much less any appreciation of a method of administering such a combination in the particular population of individuals and for the particular disorders recited in claim 21. Only through the use of applicants' own

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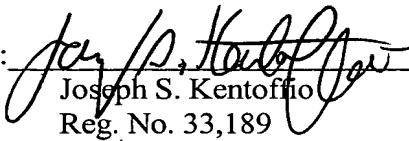
teachings can the particular method defined by claim 21 be derived from Mortimer's general comments regarding progestins and folic acid. [Such hindsight reconstruction of the present invention to bolster the prior art is clearly impermissible and does not provide the proper basis for a rejection under § 102.] #3

Accordingly, applicants request that the rejection of claim 21 as being anticipated by Mortimer be withdrawn and that claim 21 be passed to allowance at the earliest possible date.

Applicants do not believe that any fees are required in connection with the filing of this Response. However, should any fees be required please charge them to Deposit Account No. 10-0750/ORT-1316/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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Dated: September 18, 2001